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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/675,518

**Applicant(s)**

DREWES ET AL.

**Examiner**

BJ Forman

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-852) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

**FINAL ACTION**

1. This action is in response to papers filed 27 February 2003 in which claims 63 and 79 were amended and claims 83-91 were canceled. The amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of 21 October 2002 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections in the Office Action of 21 October 2002 under 35 U.S.C. 102(e) and 103(a) are maintained. All of the arguments have been thoroughly reviewed and are discussed below.

Currently claims 51-82 are under prosecution.

***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the parent application 08/742,255 filed 31 October 1996 does not provide adequate support under 35 U.S.C. 112 for claims 53, 58-62, 64, 65, 68, 69, 74-78, 80 and 81 of this application. Specifically, the '255 application does not provide support for the instantly claimed "varying the sp<sup>2</sup> and sp<sup>3</sup> character of the diamond-like carbon" recited in claims 53 & 69; the diamond-like compounds recited in claims 58-60 & 74-76; the support material that is not compatible with high temperatures as recited in claims 61, 62, 77 & 78; the capture molecules recited in claim 68; and the hardness of the diamond-like carbon recited in claims 64, 65, 80 and 81.

Because the '255 application does not teach the above limitations, the '255 application does not provide adequate support under 35 U.S.C. 112 for instant claims 53, 58-62, 64, 65, 68, 69, 74-78, 80 and 81. Therefore, the effective filing date for instant claims 53, 58-62, 64,

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65, 68, 69, 74-78, 80 and 81 is the filing date of parent application 08/950,963 i.e. 15 October 1997.

#### **Remarks**

The above statement regarding priority is reiterated from the previous Office Action. In responding to the previous office action, Applicant did not provide any comments regarding the above statement.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 51, 52, 55-60, 66-68, 71-76 and 82 are rejected under 35 U.S.C. 102(e) as being anticipated by Kobashi (U.S. Patent No. 5,777,372, filed 1 March 1996).

Regarding Claim 51, Kobashi discloses a support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface and wherein the attachment layer is adapted for capture of the analyte of interest for detecting in the assay by binding the analyte directly to

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the diamond-like carbon (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11).

Regarding Claim 52, Kobashi discloses the support wherein the attachment layer comprises a layer of diamond-like carbon of between about 50 Å to about 3000 Å (Column 7, lines 10-22).

Regarding Claim 55, Kobashi discloses the support wherein the support further comprises an optically functional layer between the support and the attachment layer (Column 10, lines 8-49).

Regarding Claim 56, Kobashi discloses the support wherein the support provides a change in optical thickness upon binding the analyte (Column 10, lines 8-49).

Regarding Claim 57, Kobashi discloses the support wherein the support is configured to provide laminar flow across the support (Fig. 7-15).

Regarding Claim 58, Kobashi discloses the support wherein the attachment layer comprises diamond-like carbon selected from the group consisting of synthetic diamond, natural diamond, and polycrystalline diamond (Column 15, lines 58-64).

Regarding Claim 59, Kobashi discloses the support wherein the diamond-like carbon comprises non-carbon material (Column, 10, line 63-Column 11, line 11).

Regarding Claim 60, Kobashi discloses the support wherein the non-carbon material is hydrogen (Column, 10, line 63-Column 11, line 11).

Regarding Claim 66, Kobashi discloses the support wherein the support is a biosensor (Abstract and Claim 1).

Regarding Claim 67, Kobashi discloses a support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface wherein the attachment layer comprises a layer of diamond-like carbon of between about 50 Å to about 3000 Å (Column 7, lines 10-22) and wherein the attachment layer a capture molecule bound to the diamond-like carbon for specific

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capture of an analyte by binding the analyte to said capture molecule (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11).

Regarding Claim 68, Kobashi discloses the support wherein the capture molecule is an enzyme (Column 11, lines 12-22 and Table 1).

Regarding Claim 71, Kobashi discloses the support wherein the support further comprises an optically functional layer between the support and the attachment layer (Column 10, lines 8-49).

Regarding Claim 72, Kobashi discloses the support wherein the support provides a change in optical thickness upon binding the analyte (Column 10, lines 8-49).

Regarding Claim 73, Kobashi discloses the support wherein the support is configured to provide laminar flow across the support (Fig. 7-15).

Regarding Claim 74, Kobashi discloses the support wherein the attachment layer comprises diamond-like carbon selected from the group consisting of synthetic diamond, natural diamond, and polycrystalline diamond (Column 15, lines 58-64).

Regarding Claim 75, Kobashi discloses the support wherein the diamond-like carbon comprises non-carbon material (Column, 10, line 63-Column 11, line 11).

Regarding Claim 76, Kobashi discloses the support wherein the non-carbon material is hydrogen (Column, 10, line 63-Column 11, line 11).

Regarding Claim 82, Kobashi discloses the support wherein the non-carbon material is hydrogen (Column, 10, line 63-Column 11, line 11).

### **Response to Arguments**

5. Applicant argues that Kobashi et al teach an analyte-specific binding agent on the support and hence do not teach or suggest an assay support as instantly claimed i.e. having an attachment layer adapted to directly bind an analyte of interest. The argument has been considered but is not found persuasive because the claims are drawn to a support "comprising"

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an attachment layer adapted for capture.....by binding the analyte directly to the diamond-like carbon. The support, as claimed, requires that the attachment layer be adapted. Kobashi et al specifically teach their attachment layer is adapted for binding the analyte (Column 10, lines 63-Column 11, line 21) wherein the analyte binds to the diamond-like carbon. Applicant appears to be arguing that the analyte binding of Kobashi et al is not directly to the diamond-like carbon. Applicant point to the specification to define the direct binding. The cited passage reads:

By "attachment layer" is meant any material or materials which promote or increase the binding of the receptive material to either the support or the optically functional layer, if it is present in the device. When no receptive layer is utilized, the attachment layer non-specifically binds the analyte.

The cited passage does not define "direct binding" but instead teaches that the attachment layer promotes binding of the receptive material or specifically binds the analyte. Furthermore, the open claim language "an attachment layer comprising" encompasses any additional components of the Kobashi et al attachment layer.

Therefore, the analyte binding of Kobashi et al is encompassed by the instant claims because the attachment layer of Kobashi et al specifically binds the analyte.

Applicant argues that Kobashi et al do not teach an attachment layer comprising an attachment layer comprising diamond-like carbon between about 50 Å and about 3000 Å as claimed because the diamond-like carbon of Kobashi et al is 1,000-500,000 Å. The argument has been considered but is not found persuasive because the instant claims are broadly drawn to an attachment layer comprising a diamond-like of between about 50 Å and about 3000 Å (about 500 Å, Claim 67). The open claim language "comprising" and the broad range of between about 50 Å and about 3000 Å in combination broadly define the attachment layer.

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case

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determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. (MPEP § 2131.03).

Because the attachment layer is so broadly defined as comprising a diamond-like of between about 50 Å and about 3000 Å (about 500 Å, Claim 67) and because Kobashi et al teach the claimed components of the attachment layer having ranges which touch and/or overlap, the attachment layer of Kobashi et al is encompassed by the broadly claimed attachment layer.

Applicant argues that Kobashi et al do not teach or suggest an optically functional layer as defined by the specification. The argument has been considered but is not found persuasive because while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Kobashi et al teach that their support comprises an optically functional layer i.e. photosensitive (Column 10, lines 8-25). As such, Kobashi et al teach the support as claimed.

Applicant argues that Kobashi et al do not refer to laminar flow through or across the device and further argues that the fact that such a characteristic may occur is not sufficient to establish inherency. The argument has been considered but is not found persuasive because the claim is drawn to a support which "provides laminar flow through or across the support". The claims does not recite structural limitations which define the support over that of Kobashi et al.



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The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Because the courts have stated that an apparatus must be distinguished from the prior art in terms of structure rather than function and because Kobashi et al disclose the claimed structural components, Kobashi et al disclose the support as claimed.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 53, 54, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi (U.S. Patent No. 5,777,372, filed 1 March 1998) in view of Yu (U.S. Patent No. 5,273,788, issued 28 December 1993).

Regarding Claim 53, Kobashi teaches a support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface and wherein the attachment layer is adapted for

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capture of the analyte of interest for detecting in the assay by binding the analyte directly to the diamond-like carbon (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11) wherein hydrophobicity is controlled to optimize functionality (Column 5, lines 29-31) but they are silent regarding the control of hydrophobicity results from varying the  $sp^2$  and  $sp^3$  character of the diamond-like carbon. However, Yu teach variations in  $sp^2$  and  $sp^3$  characteristics which determine the hydrophobicity the diamond-like carbon films was well known in the art at the time the claimed invention was made as taught by Yu. Specifically, Yu teaches that the diamond-like film characteristics e.g. hydrophobicity are controlled by altering the  $sp^2$  and  $sp^3$  ratio as desired during formation of the film (Column 3, lines 15-35 and Column 3, line 54-Column 4, line 16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the controlled film formation taught by Yu to thereby vary the hydrophobicity of the diamond-like carbon attachment later of the support of Kobashi based on their suggestion to vary the hydrophobicity of the attachment layer to optimize attachment of the capture molecule for the obvious benefits of optimizing functionality of the support as taught by Kobashi (5, lines 29-31).

Regarding Claim 54, Kobashi teaches the support comprising diamond-like carbon is illuminated for analysis of analyte binding (Column 17, lines 27-33) but they are silent regarding its function as an antireflective layer. However, it was known in the art at the time the claimed invention was made that diamond-like coatings are antireflective as taught by Yu (Column 1, lines 27-34). Therefore, the diamond-like coating of Kobashi is antireflective.

Regarding Claim 69, Kobashi teaches the support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface wherein the attachment layer comprises a layer of diamond-like carbon of between about 50 Å to about 3000 Å (Column 7, lines 10-22) and wherein the attachment layer a capture molecule bound to the diamond-like carbon for specific capture of an analyte by binding the analyte to said capture molecule (Column 10, line 26-

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Column 12, line 33; Column 15, lines 58-64; Fig. 21-23, and Claim 11) wherein hydrophobicity is controlled to optimize functionality (Column 5, lines 29-31) but they are silent regarding the control of hydrophobicity results from varying the  $sp^2$  and  $sp^3$  character of the diamond-like carbon. However, Yu teach variations in  $sp^2$  and  $sp^3$  characteristics which determine the hydrophobicity the diamond-like carbon films was well known in the art at the time the claimed invention was made as taught by Yu. Specifically, Yu teaches that the diamond-like film characteristics e.g. hydrophobicity are controlled by altering the  $sp^2$  and  $sp^3$  ratio as desired during formation of the film (Column 3, lines 15-35 and Column 3, line 54-Column 4, line 16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the controlled film formation taught by Yu to thereby vary the hydrophobicity of the diamond-like carbon attachment later of the support of Kobashi based on their suggestion to vary the hydrophobicity of the attachment layer to optimize attachment of the capture molecule for the obvious benefits of optimizing functionality of the support as taught by Kobashi (5, lines 29-31).

Regarding Claim 70, Kobashi teaches the support comprising diamond-like carbon is illuminated for analysis of analyte binding (Column 17, lines 27-33) but they are silent regarding its function as an antireflective layer. However, it was known in the art at the time the claimed invention was made that diamond-like coatings are antireflective as taught by Yu (Column 1, lines 27-34). Therefore, the diamond-like coating of Kobashi is antireflective.

It is noted that the courts have stated that chemical compositions and its properties are inseparable. Therefore, the properties of the claimed diamond-like carbon are necessarily present in the diamond-like carbon of Kobashi

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.01.

### Response to Arguments

8. Applicant reiterates the arguments regarding direct binding of the analyte; attachment layer comprising diamond-like carbon between about 50 Å and about 3000 Å; and optically functional layer. The arguments have been considered and addressed above.

Applicant argues that while Kobashi et al teach that hydrophobicity by be controlled, nothing in Yu indicates that it would be desirable or possible to determine hydrophobicity by preselecting the  $sp^2$  and  $sp^3$  ratio and therefore, the skilled artisan would not be motivated to preselect the  $sp^2$  and  $sp^3$  characteristics. The argument has been considered but is not found persuasive because as stated above, Kobashi et al specifically teach that hydrophobicity is controlled to optimize functionality (Column 5, lines 29-31) and Yu teach variations in  $sp^2$  and  $sp^3$  characteristics which determine the hydrophobicity the diamond-like carbon films (Column 3, lines 15-35 and Column 3, line 54-Column 4, line 16). As such, one of ordinary skill in the art would have been motivated to combine the teaching of Kobashi et al and Yu to obtain the claimed  $sp^2$  and  $sp^3$  ratio to thereby control hydrophobicity for the obvious benefits of optimizing functionality of the support as taught by Kobashi (5, lines 29-31).

Applicant argues that the examiner has not supported the assertion that the diamond-like carbon of Kobashi et al is anti-reflective. The argument has been considered but is not found persuasive because as stated above, Yu defines diamond-like carbon as anti-reflective (Column 1, lines 27-34). Therefore, the diamond-like coating of Kobashi is antireflective.

Applicant further argues that "antireflective layer must be an odd number of quarter wavelengths (relative to the incident light) in order to achieve reflections that are  $\pi$  radians out of phase to provide the cancellation required for antireflection. Furthermore, light reflected from the outer layer of the anti-reflection coating and light reflected from the surface of the substrate must have the some intensity in order to cancel one another. In contrast, the substrate surface in the '372 patent is designed to absorb light (thereby generating an

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electronic signal), and would thus not be compatible with the provision of an antireflective layer." In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, Yu defines diamond-like carbon as anti-reflective. Because the claims are merely drawn to an antireflective layer and because Kobashi et al teach a diamond-like carbon layer which Yu defines as anti-reflective, Kobashi teach the claimed anti-reflective layer.

9. Claims 61-63 and 77-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi (U.S. Patent No. 5,777,372, filed 1 March 1996) in view of Turner et al (U.S. Patent No. 5,624,537, filed 20 September 1994).

Regarding Claims 61-63, Kobashi teaches the support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface and wherein the attachment layer is adapted for capture of the analyte of interest for detecting in the assay by binding the analyte directly to the diamond-like carbon (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11) but they are silent regarding the support further comprising a material that is not compatible with high temperatures (Claim 61) with temperatures greater than 100° C (Claim 62) wherein the material that is not compatible with high temperatures is selected from the group consisting of cellulose, acetate, PETE, polyester, polycarbonate, nylon, filter paper, polysulfones, polypropylene and polyurethane (Claim 63). However, biosensors

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comprising the claimed cellulose and filter paper were well known in the art at the time the claimed invention was made as taught by Turner et al. Specifically, they teach that the cellulose matrix or filter paper allows for efficient and reliable feedback control for the optimization of reaction conditions (Column 4, lines 46-56 and Column 29, lines 36-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the support surface of Kobashi by adding a cellulose matrix or filter paper to the support thereby providing efficient and reliable feedback control for the expected benefit of optimizing reaction conditions as taught by Turner et al (Column 4, lines 46-56 and Column 29, lines 36-49).

Regarding Claims 77-79, Kobashi teaches the support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface wherein the attachment layer comprises a layer of diamond-like carbon of between about 50 Å to about 3000 Å (Column 7, lines 10-22) and wherein the attachment layer a capture molecule bound to the diamond-like carbon for specific capture of an analyte by binding the analyte to said capture molecule (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11) but they are silent regarding the support further comprising a material that is not compatible with high temperatures (Claim 77) with temperatures greater than 100° C (Claim 78) wherein the material that is not compatible with high temperatures is selected from the group consisting of cellulose, acetate, PETE, polyester, polycarbonate, nylon, filter paper, polysulfones, polypropylene and polyurethane (Claim 79). However, biosensors comprising the claimed cellulose and filter paper were well known in the art at the time the claimed invention was made as taught by Turner et al. Specifically, they teach that the cellulose matrix or filter paper allows for efficient and reliable feedback control for the optimization of reaction conditions (Column 4, lines 46-56 and Column 29, lines 36-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the

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support surface of Kobashi by adding a cellulose matrix or filter paper to the support thereby providing efficient and reliable feedback control for the expected benefit of optimizing reaction conditions as taught by Turner et al (Column 4, lines 46-56 and Column 29, lines 36-49).

#### **Response to Arguments**

10. Applicant argues that the above rejection is based on *post hoc* hindsight analysis. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. Claims 64, 65, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobashi (U.S. Patent No. 5,777,372, filed 1 March 1996) in view of Choi et al (U.S. Patent No. 5,883,769, filed 30 June 1997).

Regarding Claim 64, Kobashi teaches the support comprising a surface on which an assay for an analyte of interest can be preformed comprising: an attachment layer comprising diamond-like carbon on the support surface and wherein the attachment layer is adapted for capture of the analyte of interest for detecting in the assay by binding the analyte directly to the diamond-like carbon (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11) but they are silent regarding the hardness of the diamond-like carbon. However, the properties of diamond-like carbon were well known in the art as taught by Choi et

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al. Specifically, Choi et al teach the hardness of diamond-like carbon is between about 15 to about 50 Gpa (Table 1, Column 3, lines 47-62). Therefore, the diamond-like carbon of Kobashi has a hardness of between about 15 to about 50 Gpa as claimed.

Regarding Claim 65, Kobashi teaches the support comprises diamond-like carbon (Abstract and Column 15, lines 58-64) but they are silent regarding the refractive index. However, the properties of diamond-like carbon were well known in the art at the time the claimed invention was made as taught by Choi et al. Specifically, Choi et al teach the refractive index of diamond-like carbon is about 1.5 to about 2.2 (Table 1, Column 3, lines 47-62). Therefore, the diamond-like carbon of Kobashi has a refractive index of about 1.5 to about 2.2 as claimed.

Regarding Claim 80, Kobashi teaches the support comprising a surface on which an assay for an analyte of interest can be performed comprising: an attachment layer comprising diamond-like carbon on the support surface wherein the attachment layer comprises a layer of diamond-like carbon of between about 50 Å to about 3000 Å (Column 7, lines 10-22) and wherein the attachment layer a capture molecule bound to the diamond-like carbon for specific capture of an analyte by binding the analyte to said capture molecule (Column 10, line 26-Column 12, line 33; Column 15, lines 58-64; Fig. 21-23; and Claim 11) but they are silent regarding the hardness of the diamond-like carbon. However, the properties of diamond-like carbon were well known in the art as taught by Choi et al. Specifically, Choi et al teach the hardness of diamond-like carbon is between about 15 to about 50 Gpa (Table 1, Column 3, lines 47-62). Therefore, the diamond-like carbon of Kobashi has a hardness of between about 15 to about 50 Gpa as claimed.

Regarding Claim 81, Kobashi teaches the support comprises diamond-like carbon (Abstract and Column 15, lines 58-64) but they are silent regarding the refractive index. However, the properties of diamond-like carbon were well known in the art at the time the claimed invention was made as taught by Choi et al. Specifically, Choi et al teach the



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refractive index of diamond-like carbon is about 1.5 to about 2.2 (Table 1, Column 3, lines 47-62). Therefore, the diamond-like carbon of Kobashi has a refractive index of about 1.5 to about 2.2 as claimed.

It is noted that the courts have stated that chemical compositions and its properties are inseparable. Therefore, the properties of the claimed diamond-like carbon are necessarily present in the diamond-like carbon of Kobashi.

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.01.

#### **Response to Arguments**

12. Applicant argues that the Choi et al reference is non-analogous art that would not be considered reasonably pertinent to the problems of biosensor design. The argument has been considered but is not found persuasive because both Kobashi et al and Choi et al are concerned with diamond-like carbons. Therefore, one of ordinary skill in the diamond-like carbon art would have been motivated to combine the teachings of Kobashi et al and Choi et al based on their common interest i.e. diamond-like carbon.

Applicant further argues that the obviousness rejection is based on *post hoc* hindsight analysis. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 51-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 11, 23-34 and 38-50 of copending Application No. 08/950,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a solid support comprising an attachment layer comprising diamond-like carbon and differ only in the scope of the claims. Specifically, the instant application broadly claims the genus solid support and the '963 claims the species solid support wherein some of the species further comprises an optically functional layer and/or provide for sample flow. However, the open claim language "comprising" recited in the instant claims encompasses the additional components of the '963 species. Additionally, instant claims 55, 57, 71 and 73 recite the '963 species limitations i.e. optically functional layer and/or provide for sample flow. Because the instantly claimed solid support is a genus of the '963 solid support species and because instant claims 55, 57, 71 and 73 recite the species limitations, the instant claims are obvious in view of the '963 solid support. The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Response to Comments**

15. Applicant comments that because the instant claims are in allowable form and because the provisional double patenting rejection is the only remaining rejection, the examiner should withdraw the rejection and permit the claims to issue.

The comments are acknowledged but are deemed moot in view of the fact that the provisional double patenting rejection is not the only remaining rejection. As such, the rejection is maintained.

**16. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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**Conclusion**

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
May 27, 2003